No. 18-481

IN THE

Supreme Court of the United States

FOOD MARKETING INSTITUTE,
Petitioner,

v.

ARGUS LEADER MEDIA, D/B/A ARGUS LEADER,
Respondent.

On Writ of Certiorari to the
United States Court of Appeals
for the Eighth Circuit

BRIEF OF AMICI CURIAE PUBLIC CITIZEN, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, AND COLLABORATION FOR RESEARCH INTEGRITY AND TRANSPARENCY IN SUPPORT OF RESPONDENT

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INTEREST OF AMICI CURIAE[1]

Amici are three organizations that submit Freedom of Information Act (FOIA) requests and rely on agencies' FOIA disclosures to access information about the government's work protecting consumer and patient health. Amici submit this brief to highlight that petitioner Food Marketing Institute's (FMI) position—that the longstanding understanding of exemption 4 should be rejected in favor of a far broader reading—threatens to undermine important health and safety interests, including the ability of the public to hold federal agencies accountable and to ensure effective government oversight of food, drugs, and related products.

Public Citizen is a consumer advocacy organization with members and supporters in all 50 states. Since its founding in 1971, Public Citizen has supported government transparency and relied on FOIA as an important tool for learning about government activities. In particular, Public Citizen uses FOIA to obtain information about federal agencies' regulation of products that impact consumers' health and safety, often through FOIA requests for information submitted to agencies by regulated entities, such as pharmaceutical or automobile companies. Public Citizen has used information obtained through FOIA to advocate for government action to better protect the public and to alert the public about public health and safety concerns. Public Citizen has significant expertise in FOIA practice, and it has litigated many FOIA cases, including cases involving exemption 4.

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[1] This brief was not written in whole or in part by counsel for a party. No one other than amici curiae or their counsel made a monetary contribution to preparation or submission of this brief. Counsel for both parties have consented in writing to its filing.

The Center for Science in the Public Interest (CSPI) is a nonprofit, nonpartisan consumer advocacy organization. CSPI conducts research, promotes evidence-based policies, and provides consumers with current, useful information related to their health. CSPI uses FOIA to obtain information that nongovernment entities submit in order to help the public make better informed decisions and to petition agencies to remove dangerous ingredients from the market. CSPI routinely uses FOIA to garner information related to foodborne illness.

The Collaboration for Research Integrity and Transparency (CRIT) is an interdisciplinary initiative of Yale Law School, Yale Medical School, and Yale School of Public Health. CRIT's mission is to promote public health by improving the transparency and integrity of biomedical and clinical research. CRIT regularly uses FOIA to obtain information from the Food and Drug Administration and other agencies because such data helps reveal regulatory failures that put Americans' health and safety at risk. This information is often submitted by pharmaceutical and medical device companies and other non-governmental entities, potentially implicating exemption 4. CRIT attorneys have also litigated FOIA suits challenging the FDA's withholding of such information, including data on the safety and efficacy of FDA-approved drugs that is used by researchers to evaluate both the drugs and the FDA regulatory process.

SUMMARY OF ARGUMENT

FOIA was enacted to help "ensure an informed citizenry, vital to the functioning of a democratic society, needed to check against corruption and to hold the governors accountable to the governed." *NLRB v. Robbins Tire & Rubber Co.*, 437 U.S. 214, 242 (1978). The statute

achieves this goal by requiring agencies to disclose records in response to requests, 5 U.S.C. § 552(a)(3), and by requiring agencies to disclose certain records proactively, *id.* § 552(a)(1)–(2), subject to nine exclusive exemptions, *id.* § 552(b).

At issue here is exemption 4, which exempts from disclosure two categories of information: "trade secrets" and "commercial or financial information obtained from a person and privileged or confidential." *Id.* § 552(b)(4). The definition of "confidential" adopted by the D.C. Circuit 45 years ago in *National Parks & Conservation Ass'n v. Morton*, 498 F.2d 765 (D.C. Cir. 1974), and now applied by every Circuit to have considered the issue, Pet Br. 38 & nn.23 & 24, properly construes exemption 4 to encompass only commercial or financial information disclosure of which would cause substantial competitive harm. The language of exemption 4 as a whole, FOIA's purpose, and its legislative history confirm the *National Parks* definition of "confidential."

In stark contrast to FMI's reading of exemption 4, the *National Parks* standard is a crucial tool that enables the public to learn "what their government is up to." *DOJ v. Reporters Comm. for Freedom of the Press*, 489 U.S. 749, 773 (1989) (emphasis omitted) (citation omitted). Members of the public regularly use FOIA to obtain vital public health and safety information submitted to the government by non-governmental entities. Such information often provides context for government action and inaction, allowing the public to assess the effectiveness of government regulation, to petition the government to take action where necessary, and to make better informed choices. As described below, the *National Parks* standard properly allows the public access to a great deal of information concerning federal agencies' work to protect public health

and safety. Much of that vital information would likely be inaccessible to the public under FMI's proposed reading.

Additionally, the longstanding construction of exemption 4, applied for decades by courts nationwide, is sensible and workable. FMI's contrary argument amounts to little more than a policy disagreement with Congress about the scope of exemption 4. The current construction of exemption 4 reflects the balance struck by Congress between disclosure and privacy; FMI's alternative construction would result in an expansive exemption favoring broad withholding, contrary to FOIA's purpose, as reiterated by this Court.

ARGUMENT

I. The *National Parks* standard properly defines the scope of FOIA exemption 4.

Exemption 4 protects from disclosure "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). The statute does not define "trade secrets," "commercial or financial information," "privileged," or "confidential." *See id.* In the absence of a statutory definition, *National Parks* correctly looked to the text, the statutory purpose, and the legislative history to conclude that whether information submitted to the government falls within exemption 4 is not determined simply by "[w]hether particular information would customarily be disclosed to the public by the person from whom it was obtained." 496 F.2d at 767. Rather, aside from trade secrets, commercial or financial information, unless it is privileged, is protected as "confidential" under exemption 4 if disclosure is likely "to cause substantial harm to the competitive position of the person from whom the information was obtained." *Critical Mass Energy Project v.*

Nuclear Regulatory Comm'n, 975 F.2d 871, 878 (D.C. Cir. 1992) (en banc) (quoting *National Parks*, 498 F.2d at 770)).

The *National Parks* standard has been uniformly adopted by every court of appeals to have considered the issue. *See 9 to 5 Org. for Women Office Workers v. Bd. of Governors of the Fed. Reserve Sys.*, 721 F.2d 1, 7–10 (1st Cir. 1983); *Cont'l Stock Transfer & Trust Co. v. SEC*, 566 F.2d 373, 375 (2d Cir. 1977); *OSHA Data/CIH, Inc. v. DOL*, 220 F.3d 153, 162 & n.24 (3d Cir. 2000); *Acumenics Research & Tech. v. DOJ*, 843 F.2d 800, 807 (4th Cir. 1988); *Cont'l Oil Co. v. Fed. Power Comm'n*, 519 F.2d 31, 35 (5th Cir. 1975); *Gen. Elec. Co. v. U.S. Nuclear Regulatory Comm'n*, 750 F.2d 1394, 1402 (7th Cir. 1984); *Contract Freighters, Inc. v. Sec'y of U.S. Dep't of Transp.*, 260 F.3d 858, 861 (8th Cir. 2001); *Pac. Architects & Eng'rs Inc. v. U.S. Dep't of State*, 906 F.2d 1345, 1347 (9th Cir. 1990); *Anderson v. Dep't of Health & Human Servs.*, 907 F.2d 936, 946 (10th Cir. 1990); *Sharkey v. FDA*, 250 F. App'x 284, 288 (11th Cir. 2007).

A. As with any question of statutory construction, consideration of the scope of a FOIA exemption starts with the statutory text. *Milner v. Dep't of the Navy*, 562 U.S. 562, 569 (2011). FMI relies almost exclusively on dictionary definitions of "confidential" as the basis for its assertion that the term encompasses any information that is "kept private and not publicly disclosed." Pet. Br. 17–19. But the text of exemption 4 is not limited to a single word. The relevant provision exempts "trade secrets and commercial or financial information obtained from a person and privileged or confidential." Respondent's brief discusses the statutory text at length, and we will not repeat those arguments here.

Statutory text, however, must be read in its proper context, not viewed in isolation. *Koons Buick Pontiac GMS*

v. Nigh, 543 U.S. 50, 60 (2004) (citing *United Sav. Ass'n of Tex. v. Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 371 (1988), and *McCarthy v. Bronson*, 500 U.S. 136, 139 (1991)). "[T]he plainness or ambiguity of statutory language is determined not only by reference to the language itself, but as well by the specific context in which that language is used, and the broader context of the statute as a whole." *Yates v. United States*, 135 S. Ct. 1074, 1081–82 (2015) (plurality opinion) (brackets omitted) (quoting *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997)).

The context of FOIA strongly supports the longstanding narrow reading of "confidential." This Court "ha[s] often noted 'the Act's goal of broad disclosure' and insisted that the exemptions be 'given narrow compass.'" *Milner*, 562 U.S. at 571 (quoting *DOJ v. Tax Analysts*, 492 U.S. 136, 151 (1989)); *see also Dep't of Interior v. Klamath Water Users Protective Ass'n*, 532 U.S. 1, 7–8 (2001) ("These limited exemptions do not obscure the basic policy that disclosure, not secrecy, is the dominant objective of the Act." (internal brackets omitted) (quoting *Dep't of Air Force v. Rose*, 425 U.S. 352, 361 (1976))); *DOJ v. Landano*, 508 U.S. 165, 181 (1993) (explaining the Court "has an obligation to construe FOIA exemptions narrowly in favor of disclosure"). FMI's proposed definition is irreconcilable with the Court's repeated statements, over many decades, that the exemptions should be narrowly construed. Its reading of exemption 4 would swallow virtually all information submitted by non-governmental entities. If "confidential" information meant *all* information that is "kept private and not publicly disclosed," Pet. Br. 16, the only submitted information that would fall outside exemption 4 would be information that is *already* publicly disclosed—for which there is no need for a FOIA request. Thus, un-

der FMI's reading, exemption 4 would have the same effect as if it exempted "all commercial or financial information obtained from a person."

Consideration of the context of FOIA also undercuts the government's proposed alternative definition of "confidential"—that information is also "confidential" if a government official led the submitter to expect that the government would not publicly disclose it. *See* U.S. Br. 15. The government's proposed definition finds little support in the language of exemption 4, which the government effectively revises to make nearly every word superfluous. And the theory that, in a statute enacted to mandate disclosure of government information, subject only to specifically stated exemptions, Congress chose to allow agency employees to deem a wide swath of information exempt at will or whim turns FOIA on its head. Such a reading of exemption 4 stands in marked tension with FOIA's purpose, as repeatedly acknowledged by this Court.

As the Court has recognized, FOIA marked a sea change in the public availability of government records. *See Klamath Water Users Protective Ass'n*, 532 U.S. at 16 ("In FOIA, after all, a new conception of Government conduct was enacted into law, 'a general philosophy of full agency disclosure.'" (quoting *Tax Analysts*, 492 U.S. at 142)). FOIA's predecessor "was plagued with vague phrases," allowing the government, for example, to withhold any information that, in its sole judgment, "requir[ed] secrecy in the public interest." *EPA v. Mink*, 410 U.S. 73, 79 (1973) (internal quotation marks omitted). "In enacting the FOIA, Congress intended 'to curb this unbridled discretion' by 'closing the loopholes which allow agencies to deny legitimate information to the public.'" *Tax Analysts*, 492 U.S. at 151 (internal quotation marks and brackets omitted) (quoting *GTE Sylvania, Inc. v. Con-*

sumers Union of U.S., Inc., 445 U.S. 375, 385 (1980)). Allowing the government to determine unilaterally whether to deem information "confidential" would give the government the "unbridled discretion" that Congress sought to end. *See Bristol-Myers Co. v. FTC*, 424 F.2d 935, 938 (D.C. Cir. 1970) ("When Congress acted to close those loopholes [by enacting FOIA], it clearly intended to avoid creating new ones.").

Taking into account both "the specific context in which ['confidential'] is used, and the broader context of [FOIA] as a whole," *Yates*, 135 S. Ct. at 1081–82, the courts of appeals have properly construed "confidential" information, under exemption 4, to mean information the disclosure of which would "cause substantial harm to the competitive position of the person from whom the information was obtained."[2] *National Parks*, 498 F.2d at 770.

Importantly, this case presents significantly different circumstances from those in *Milner v. Department of the Navy*, where the Court rejected a contention that the D.C. Circuit's interpretation of exemption 2 should stand because it "'ha[d] been consistently relied upon and followed for 30 years' by other lower courts." 562 U.S. at 575 (quoting *id.* at 585 (Breyer, J., dissenting)). The D.C. Circuit's interpretation of exemption 2 had only been adopted by

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[2] *National Parks* also defined "confidential" information to include information disclosure of which would "impair the Government's ability to obtain necessary information in the future." 498 F.2d at 770. Here, the government disclaims any argument that future government impairment should be considered under exemption 4. U.S. Br. 19–20 ("The government's ability to obtain *other* information in the future does not determine whether the particular commercial information at issue in the FOIA request is currently 'confidential.'"). Amici agree that government impairment is not properly considered under exemption 4, which is concerned with harm to non-governmental entities that submit information to the government.

three additional circuits, and three other circuits had reached a *contrary* conclusion, resulting in "a 4 to 3 split among the Circuits." *Id.* at 576–77. Here, by contrast, *National Parks* has been accepted by *every* circuit to have considered the issue: Ten circuits have adopted *National Parks* in published opinions, and one has applied it in an unpublished case. Pet. Br. 38 nn.23 & 24.

Moreover, the interpretation of exemption 2 challenged in *Milner* broadened that exemption, essentially creating an additional exemption. That result ran directly counter to FOIA's purpose and this Court's case law requiring that "exemptions be 'given a narrow compass.'" *Milner*, 562 U.S. at 571 (quoting *Tax Analysts*, 492 U.S. at 151). Here, FMI asks the Court to do the opposite: reverse a longstanding *narrow* construction to make the exemption substantially broader. In light of FOIA's text and purpose, the Court should definitively reject this result.

B. FMI posits that exemption 4 may include a "buffer zone"—that is, that Congress may have crafted exemption 4 more broadly than necessary, ensuring protection for records the disclosure of which could cause substantial competitive harm by providing protection for a far broader category of records. Pet. Br. 27 n.14. This suggestion runs counter to the many cases directing that the exemptions be narrowly construed. *See supra* pp. 6–7.

Furthermore, the FOIA Improvement Act of 2016, Pub. L. No. 114-185, 130 Stat. 538, explicitly forecloses assertions that records may be exempt under exemption 4 even if they do not implicate the interests Congress sought to protect in enacting the exemption. In that Act, Congress amended FOIA to, among other things, raise the threshold for withholding. The Act directs that an agency "shall withhold information under [FOIA] only if—(I) the agency reasonably foresees that disclosure

would harm an interest protected by an exemption"; or "(II) disclosure is prohibited by law." 5 U.S.C. § 552(a)(8)(A). Because the 2016 Act applies only to FOIA requests made after the date of enactment, *see* FOIA Improvement Act of 2016, Pub. L. No. 114-185, § 6, 130 Stat. 544–45, this provision does not apply to the 2011 FOIA request at issue here. App. 10a. Nonetheless, section 552(8)(a) applies to most pending FOIA requests (all those submitted after June 30, 2016).[3]

Accordingly, as to information submitted by a commercial entity, even if information sought through FOIA constitutes "confidential" commercial or financial information, the agency may now only withhold the information if it can establish that it is reasonably foreseeable that disclosure will "harm an interest protected by" exemption 4. 5 U.S.C. § 552(a)(8)(i)(I).

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[3] As the Senate Committee Report that accompanied the FOIA Improvement Act of 2016 makes clear, § 552(a)(8) "codifies the policy established for releasing Government information under FOIA by President Obama when he took office and confirmed by Attorney General Holder in a March 19, 2009, Memorandum to all Executive Departments and Agencies." S. Rep. No. 114-4 (2015), *as reprinted in* 2016 U.S.C.C.A.N. 321, 327–28. The Holder Memorandum referenced in the Committee Report instructed each agency not to withhold information "merely because it can demonstrate, as a technical matter, that the records fall within the scope of a FOIA exemption." Attorney General Memorandum for Executive Departments and Agencies Concerning the Freedom of Information Act, 74 Fed. Reg. 51,878, 51,879 (Oct. 8, 2009). Because the Holder Memorandum was guidance to federal agencies concerning under what circumstances the Department of Justice would defend withholdings and was "not intended to, and [did] not, create any right or benefit, substantive or procedural, enforceable at law or equity by any party against" the federal government, the memorandum speaks in terms of what agencies "should" and "should not"—rather that they "must" or "cannot"—do under this standard. *Id.* 51,879–82. With this standard now codified, the instruction is now mandatory.

Section 552(a)(8) confirms exactly the approach the D.C. Circuit took in *National Parks*, which declined to construe exemption 4 in isolation from the interests Congress sought to protect in crafting it. In *National Parks*, the D.C. Circuit looked not only at the single word "confidential" but at the congressional purpose in enacting exemption 4. *See* 498 F.2d at 767–70. The court first explained "the various exemptions included in the statute serve two interests—that of the Government in efficient operation and that of persons supplying certain kinds of information in maintaining its secrecy." *Id.* at 767. While some exemptions "serve only one or the other of the two interests," the D.C. Circuit concluded that exemption 4 "is intended to protect interests of both the Government and the individual." *Id.* In examining the interest of non-governmental entities that exemption 4 sought to protect, the D.C. Circuit determined the relevant "interest" was the protection of "valuable business information," i.e., information disclosure of which would cause competitive harm. *Id.* at 768.

In short, numerous principles of statutory construction support the courts of appeals' longstanding construction of exemption 4. As those courts have properly held, information can be withheld under exemption 4 as "confidential" commercial or financial information only if disclosure would "cause substantial harm to the competitive position of the person from whom the information was obtained." *Id.* at 770.

II. FMI's construction of exemption 4 threatens to prevent disclosure of information vital to the protection of public health and safety.

Both FMI and the government argue that release of information submitted to agencies by sources outside the government does not serve FOIA's "core purpose" of "disclosure of agency records that 'contribut[e] significantly

to public understanding *of the operations or activities of the government*,'" and that restricting disclosure of this information therefore will not impede FOIA's aims. U.S. Br. 16 (quoting *U.S. Dep't of Def. v. Fed. Labor Relations Auth.*, 510 U.S. 487, 495 (1994)); *see* Pet. Br. 33–35. But they misunderstand the critical role played by information obtained from non-governmental entities. It is not information that just happens to be in the government's possession, but information that informs government decisionmaking and often determines government policy. As Congress recognized in passing the Paperwork Reduction Act of 1980:

> [M]any federal programs attempt to serve large numbers of people in a variety of ways, such as protecting civil rights, providing decent housing and ensuring safe and healthy working conditions. In those and other areas, Congress has made critically important commitments to the people of this nation. In order to be effective, many of those programs must collect information from the public in order to make intelligent decisions on standards, benefits and other government actions.

S. Rep. No. 96-930 at 3 (1980), 1980 U.S.C.C.A.N. 6241, 6243.

Public disclosure of information submitted by a company, in turn, is often necessary to know what the "government is up to." It elucidates the basis for government action or inaction, and can reveal whether the government is effectively doing its job, whether it is efficient or wasteful, and whether a regulator is subject to "agency capture." Applying exemption 4 as long construed by the D.C. Circuit and other circuits has often enabled watchdog organizations and journalists to obtain this valuable information through FOIA. These disclosures have catalyzed

government action for public benefit and allowed the public to make better informed health and safety decisions about regulated products. In this way, disclousres through FOIA under the longstanding reading of exemption 4 have played an important role in supporting vital public protections.

Although agencies have some discretion to release exempt information, *see, e.g., Chrysler Corp. v. Brown*, 441 U.S. 281, 294 (1979), the real-world history of FOIA shows that agencies seldom exercise that discretion to disclose when the submitter objects—evidenced by the abundance of exemption 4 litigation and the paucity of "reverse-FOIA" lawsuits, in which a submitter sues the agency in an effort to block disclosure of the information it submitted.[4] Moreover, some agency regulations are explicit that the agency will not discretionarily disclose confidential commercial or financial information. *See* 21 C.F.R. § 20.61(c) ("Data and information submitted or divulged to the [FDA] which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure."). Thus, FMI's broad construction of exemption 4 would drastically curtail public access to information in the hands of federal agencies, creating risks to public health and safety. Examples abound in connection with government oversight of food, drugs, and medical devices.

Data on Dangerous Opioid Use. In 2011, the Food and Drug Administration (FDA) created a Risk Evaluation

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[4] Amici's Westlaw search for reverse-FOIA cases since 1999 found 27 such cases over that 20-year period. *See also* Paul R. Verkuil, *An Outcomes Analysis of Scope of Review Standards*, 44 Wm. & Mary L. Rev. 679, 717 n.176 (2002) (finding only 64 reported reverse-FOIA cases between 1979 and 2002, of which only 40 went to judgment).

and Mitigation Strategy (REMS) designed to oversee prescribers of a class of drugs known as Transmucosal Immediate Release Fentanyl (TIRF).[5] These are fast-acting formulations of the highly addictive drug fentanyl that pose serious risks, and the FDA has only approved them for a narrow category of opioid-tolerant cancer patients.[6] The goal of the REMS is to "mitigate the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors" by "[p]rescribing and dispensing TIRF medicines only to appropriate patients."[7]

Dr. Caleb Alexander, a professor at the Johns Hopkins Bloomberg School of Public Health, filed a FOIA request seeking information related to the REMS for a number of prescription drugs, including TIRFs.[8] Citing exemption 4, the FDA withheld certain documents and redacted others, claiming they contained confidential commercial information.[9] When Dr. Alexander, with the help of amicus

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[5] *See* FDA, *Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS)* (last modified Aug. 2017), https://www.accessdata.fda.gov/drugsatfda_docs/rems/TIRF_2017-09-07_Full.pdf.

[6] *See Selected Important Safety Information*, TIRF REMS Access (last visited Mar. 7, 2019), https://www.tirfremsaccess.com/TirfUI/rems/safetyInformation.action ("TIRF medicines are indicated only for the management of breakthrough pain in adult cancer patients 18 years of age (16 years of age and older for Actiq brand and generic equivalents) who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.").

[7] FDA, *Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS)*, *supra* n.5.

[8] Jeffrey E. Rollman et al., *Assessment of the FDA Risk Evaluation and Mitigation Strategy for Transmucosal Immediate-Release Fentanyl Products*, 321 JAMA 676, 677 (2019).

[9] *Id.*

CRIT, administratively appealed and argued the agency had failed to show the competitive harm required under exemption 4, the FDA released an additional 1,065 pages.[10] The documents revealed that the FDA had evidence that these drugs were being prescribed to patients who did not have cancer or were not opioid-tolerant and, thus, were outside the narrow group of people for whom the FDA had determined the drugs were safe.[11] Yet the FDA had taken only minor steps to address this dangerous off-label use of these drugs[12] and did not review the prescribing records of any physicians to consider disqualifying them from the program.[13]

These revelations sparked an outcry from journalists, academics, and congresspersons—ultimately prompting the FDA to review the TIRF REMS.[14] Dr. Alexander testified before an FDA advisory committee about the lack of

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[10] *Id.*

[11] *Id.* at 681–83.

[12] *Id.* at 681–82.

[13] Johns Hopkins University Bloomberg School of Public Health, *Study Finds Inadequate FDA Oversight of Prescribing of Fentanyl Products*, Medical Xpress (Feb. 19, 2019), https://medicalxpress.com/news/2019-02-inadequate-fda-oversight-fentanyl-products.html.

[14] *See, e.g.*, Emily Baumgaertner, *F.D.A. Did Not Intervene to Curb Risky Fentanyl Prescriptions*, N.Y. Times (Aug. 2, 2018), https://www.nytimes.com/2018/08/02/health/fda-fentanyl-opioid-epidemic-overdose-cancer.html; Letter from Hon. Edward Markey, U.S. Senator, to Hon. Scott Gottlieb, Commissioner, FDA (Aug. 17, 2018), https://www.markey.senate.gov/imo/media/doc/FDA%20REMS%20and%20fentanyl%2008.17.18.pdf.

efficacy of the TIRF REMS based on the produced documents.[15] And the FDA subsequently promised changes "intended to strengthen the current TIRF REMS."[16]

A manufacturer surely would not publicly disclose that a REMS was not being followed. Therefore, under FMI's broad reading, the FDA could withhold this important safety information from FOIA requesters.

Risks Posed by Drugs and Medical Devices. Each year, the FDA receives several hundred thousand reports of suspected deaths and serious injuries associated with drugs and medical devices. As part of FDA regulation of drugs and medical devices, the agency requires companies that market drugs and medical devices to submit reports concerning such "adverse events" or "adverse effects" associated with a drug or medical device throughout the product's life cycle. *See* 21 C.F.R. § 312.32 (drug investigational process adverse event reporting); § 314.80 (drug post-market adverse event reporting); § 803.10 (medical device post-market adverse event reporting); § 812.50 (medical device investigational process adverse effect reporting).

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[15] G. Caleb Alexander, Testimony for the Record Submitted to the U.S. Food and Drug Administration for the Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee, Dkt. No. FDA-2018-N-1917 (Aug. 3, 2018), https://int.nyt.com/data/documenthelper/123-fda-opioid-overdose-cancer/4be5694a2729eb5b522d/optimized/full.pdf.

[16] FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D. on the Agency's 2019 Policy and Regulatory Agenda for Continued Action to Forcefully Address the Tragic Epidemic of Opioid Abuse* (Feb. 26, 2019), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632067.htm.

The FDA has routinely made adverse event information available to the public, recognizing that it is not exempt under exemption 4.[17] The FDA proactively discloses the information, posting online a database containing post-market "adverse event reports, medication event reports and product quality complaints resulting in adverse events that [have been] submitted to FDA."[18] In addition, "[i]ndividual case safety reports from the FAERS database can also be obtained by sending a [FOIA] request to FDA."[19] *See also Citizens Comm'n on Human Rights v. FDA*, 45 F.3d 1325, 1329 (9th Cir. 1995) (noting that the FDA agrees that "individual adverse reaction reports are not exempt from disclosure" under FOIA).

Although the FDA maintains a similar public-facing database for medical device malfunctions—Manufacturer and User Facility Device Experience (MAUDE)[20]—recent investigative reporting uncovered that the FDA has maintained a "hidden database" containing reports concerning over a million incidents involving medical device malfunctions.[21] The FDA has begun requiring "place-

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[17] *See* FDA, *Electronic Reading Room* (last updated Mar. 6, 2017), https://www.fda.gov/RegulatoryInformation/FOI/ElectronicReadingRoom/default.htm.

[18] FDA, *Questions and Answers on FDA's Adverse Event Reporting System (FAERS)* (last updated June 4, 2018), https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/adversedrugeffects/default.htm.

[19] *Id.*

[20] *See* FDA, *MAUDE – Manufacturer and User Facility Device Experience* (last updated Feb. 28, 2019), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.

[21] Christina Jewett, *Hidden FDA Reports Detail Harm Caused by Scores of Medical Devices*, Kaiser Health News (Mar. 7, 2019),

holder" public reports to be filed in at least some instances, so that members of the public "may find a [placeholder] public report and submit a [FOIA] request to get information about incidents."[22] Although access to these previously hidden adverse event reports involving devices is more cumbersome than access through the MAUDE database, FOIA continues to provide the public with a vital means to obtain access.

Amicus Public Citizen regularly uses adverse event data, along with other information, to monitor the FDA's regulation of drugs and medical devices on the market. In many instances, Public Citizen has used information obtained in this way to submit comments to FDA dockets or to petition the FDA to remove dangerous drugs from the market.[23] Adverse event report information has contributed to Public Citizen citizen petitions that helped to prompt removal of 23 dangerous drugs from the market.[24]

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https://khn.org/news/hidden-fda-database-medical-device-injuries-malfunctions/.

[22] *Id.*

[23] *See, e.g.*, Public Citizen, Petition to Ban Sibutramine (Meridia) (FDA Dec. 3, 2009), https://www.citizen.org/our-work/health-and-safety/petition-ban-sibutramine-meridia; Public Citizen, Petition to Ban the Antibiotic Gatifloxacin (Tequin) (FDA May 1, 2006), https://www.citizen.org/our-work/health-and-safety/articles/petition-ban-antibiotic-gatifloxacin-tequin; Public Citizen, Petition to Withdraw Celecoxib & Valdecoxib (FDA Jan. 24, 2005), https://www.citizen.org/our-work/health-and-safety/petition-withdraw-celecoxib-valdecoxib.

[24] *See, e.g.*, FDA, *FDA Drug Safety Communication: FDA Recommends Against the Continued Use of Meridia (sibutramine)* (Oct. 8, 2010), https://www.fda.gov/Drugs/DrugSafety/ucm228746.htm; Determination that TEQUIN (Gatifloxacin) Was Withdrawn from Sale for Reasons of Safety or Effectiveness, 73 Fed. Reg. 52,357 (Sept. 9, 2008); FDA, *COX-2 Selective (Includes Bextra, Celebrex, and Vioxx)*

There can be little doubt that medical device and pharmaceutical companies typically keep private and do not publicly disclose the adverse event information that they submit to the FDA. Thus, under FMI's view, reports concerning both drugs and devices would fall within exemption 4. All FDA databases of adverse events would effectively be "hidden databases," and the public would have no avenue to uncover their contents. The lack of public access to this information would severely undermine the public's ability to monitor the adequacy and effectiveness of the FDA's regulation of drugs and medical devices, and thus to advocate for stronger protections against dangerous products.

Contamination in Drug Manufacturing Facilities. Under 21 U.S.C. § 374, the FDA is authorized to perform inspections of pharmaceutical facilities and search for, among other things, toxic hazards such as mold and bacteria. Inspection findings are documented on FDA Form 483, which is "issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of" the Food Drug and Cosmetic Act.[25]

In 2018, several FOIA requests were submitted for a Form 483 relating to an FDA inspection of Pfizer's Hospira manufacturing facility in McPherson, Kansas. The FDA subsequently published this Form 483 online in its

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and Non-Selective Steroidal Anti-Inflammatory Drugs (NSAIDs) (Apr. 7, 2005), https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm429364.htm.

[25] FDA, *FDA Form 483 Frequently Asked Questions* (last updated July 24, 2017), https://www.fda.gov/ICECI/Inspections/ucm256377.htm.

FOIA Electronic Reading Room.[26] The Hospira Form 483 revealed that, despite numerous warnings from the FDA, including a 2017 warning letter, Pfizer had failed to address ongoing manufacturing violations at the Hospira facility.[27]

Specifically, Pfizer "failed to adequately investigate 9 previous events when an unknown foreign material/gel was observed adhering to the ... filter screens [in the manufacturing facility]" even though it knew about potential contamination in its manufacturing lines.[28] Furthermore, despite identifying a "critical defect" in its manufacturing process as early as December 20, 2017, Pfizer did not modify its written procedures to address the defect until March 30, 2018, and did not implement the change until April 30, 2018.[29] The inspection report shed new light on previously reported failings in the plant's manufacturing process, such as the fact that Pfizer had to partially suspend production at the plant after finding mold contamination.[30] The report noted numerous times that Pfizer

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[26] *See* FDA, Form 483 Issued to Hospira Inc. A Pfizer Company (Aug. 8, 2018), https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm627630.pdf ("Hospira Form 483"); *see also* 5 U.S.C. § 552(a)(2)(D) (requiring agencies to publicly post in an electronic format records that have been released to any person and that either "because of the nature of their subject matter, the agency determines have become or are likely to become the subject of subsequent requests for substantially the same records" or "have been requested 3 or more times").

[27] Letter from Cheryl A. Bigham, District Director, Kansas City District, FDA Office of Regulatory Affairs, to Ian C. Reed, Chairman and CEO, Pfizer Inc. (Feb. 14, 2017), https://www.fda.gov/iceci/enforcementactions/warningletters/2017/ucm542587.htm.

[28] Hospira Form 483 at 2.

[29] *Id.* at 3.

[30] *Id.* at 1.

failed to alert the FDA when it discovered issues with its plant, failed to implement an adequate aseptic process, and failed to institute adequate inspection procedures.[31] The report also catalogued other violations of the FDA's Current Good Manufacturing Practices.[32] The release of the form resulted in extensive media coverage, forcing Pfizer to publicly confront the issues and make changes to address them—and showing that the FDA apparently had not done so.[33]

Since at least 2009, the FDA has proactively disclosed certain information from various types of inspections, including inspections of drug manufacturing facilities, in recognition of the information's usefulness in "improv[ing] the public's understanding of how the FDA works to protect the public health, provid[ing] the public with a rationale for the Agency's enforcement actions, and

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[31] *Id.* at 3, 4–6, 6–8.

[32] *Id.* at 9–10.

[33] *See, e.g.*, Eric Palmer, *Pfizer CEO: It'll Be 2020 Before Issues in Sterile Injectables Manufacturing Are Resolved*, FiercePharma (Jan. 30, 2019), https://www.fiercepharma.com/manufacturing/pfizer-ceo-indicates-it-will-be-2020-before-sterile-injectables-issues-are-resolve; Dan Stanton, *Pfizer Kansas Plant Hit By FDA 483 With 8 Repeat Observations*, BioProcess International (Dec. 10, 2018), https://bioprocessintl.com/bioprocess-insider/regulations/pfizer-kansas-plant-hit-by-fda-483-with-8-repeat-observations/; Ana Mulero, *Updated: FDA Flags Pfizer's Hospira Plant in Kansas Over Repeat 483 Citations*, Regulatory Focus (Dec. 7, 2018), https://www.raps.org/news-and-articles/news-articles/2018/12/fda-flags-pfizers-hospira-plant-in-kansas-over-re; Ben Hargreaves, *Pfizer lowers guidance due to Hospira Manufacturing Issues*, in-Pharma Technologist.com (Nov. 1, 2018), https://www.in-pharmatechnologist.com/Article/2018/11/01/Pfizer-lowers-guidance-due-to-Hospira-manufacturing-issues.

... inform[ing] the public and industry decision-making allowing them to make more informed marketplace choices and help to encourage compliance."[34] Even a quick review of the FDA Office of Regulatory Affairs' FOIA Electronic Reading Room reveals over one thousand Form 483s available for public viewing.[35]

Although Form 483s themselves are government documents, a significant portion of the information in Form 483s is "obtained from" the regulated companies and thus potentially within the reach of exemption 4.[36] Under FMI's reading, a great deal of the information on the forms would fall within the exemption. Pfizer, for example, undoubtedly would not publicly disclose information about its previous actions and findings at the Hospira facility, putting such information beyond the reach of FOIA under FMI's proposed definition.

Post-Marketing Studies of Drug Risks. When the FDA approves a new drug, it sometimes requires as a condition of approval that the drug manufacturer undertake a post-approval study, also referred to as a Phase IV Trial. These studies "are conducted after a treatment is ap-

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[34] FDA, *Inspection Citation* (last updated Feb. 13, 2019), https://www.fda.gov/ICECI/Inspections/ucm346077.htm.

[35] FDA, *ORA FOIA Electronic Reading Room* (last updated May 22, 2018), https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/default.htm ("We are making these records publicly available either (1) proactively at our discretion or (2) because they are 'frequently requested' per the Electronic Freedom of Information Act Amendments of 1996.").

[36] Several of the currently available Form 483s have some information withheld under exemption 4. *See, e.g.*, Hospira Form 483.

proved for use by the FDA [and] provide additional information including the treatment or drug's risks, benefits, and best use."[37]

When the FDA approved the drug metformin, it required a post-marketing study because of concerns about serious adverse effects. *Public Citizen Health Research Grp. v. FDA*, 964 F. Supp. 413, 414 (D.D.C. 1997). When amicus Public Citizen submitted a FOIA request for the post-marketing study protocol, the FDA asserted exemption 4. *Id.* Public Citizen filed suit, and the court, applying the *National Parks* standard, concluded that the manufacturer, which had intervened in the litigation to argue against disclosure, had not shown a likelihood that disclosure would cause competitive harm. *Id.* at 415–16. The court explained that it "found little to suggest that the details of the protocol, i.e., the parameters of the study, would reveal anything that would provide an advantage to a competitor." *Id.* at 416. The court subsequently ordered disclosure of the protocol. *See Public Citizen Health Research Grp. v. FDA*, No. 96-cv-1650 (JR) (D.D.C. Nov. 3, 1997), ECF No. 45.

Following this ruling, Public Citizen has requested through FOIA—and received—post-marketing study protocols for several additional drugs. In the immediate aftermath of the metformin decision, the FDA in response to FOIA requests continued to rely on exemption 4 to withhold protocols and released them only following the initiation of litigation; thereafter, FDA began releasing such protocols in response to FOIA requests. Public Citizen has used such protocols to evaluate the FDA's ap-

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[37] FDA, *What Are the Different Types of Clinical Research?* (last updated Jan. 4, 2018), https://www.fda.gov/forpatients/clinicaltrials/types/default.htm.

proval decisions and to assess the agency's use of post-marketing studies of drugs approved in the face of unresolved safety concerns. Under FMI's broad construction of exemption 4, this information would no longer be available to the public.

Uses of Drugs Disapproved by the FDA. When drug manufacturers submit new drug applications to the FDA for approval to market a drug, they must include "the drug product's proposed indications for use." 21 C.F.R. § 314.50(a)(1); *see also id.* § 314.50(d)(5)(ii) (requiring inclusion of "[a] description and analysis of each controlled clinical study pertinent to a proposed use of the drug"). The FDA may grant approval for none, all, or some of the proposed uses of the drug.

In the case of valdecoxib (Bextra), the FDA approved the drug for three uses but rejected its use for acute pain. Although the FDA publicly posted records related to the agency's approval for the three approved uses, it redacted and withheld records related to the disapproved use for acute pain pursuant to exemption 4 as confidential commercial information. In the meantime, an article appeared in the Journal of the American Dental Association touting Bextra's use for acute pain.[38] The article failed to mention that the FDA had *not* approved Bextra for this use. But because the FDA had redacted from its public disclosure all material related to Bextra's use for acute pain, the public did not have information to balance the article's assertions about the drug's use for acute pain.

Public Citizen submitted a FOIA request for unredacted versions of the records related to FDA's approval

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[38] Stephen E. Daniels et al., *The Analgesic Efficacy of Valdecoxib vs. Oxycodone/Acetaminophen After Oral Surgery*, 133 J. Am. Dental Ass'n 611 (2002).

of Bextra, including materials related to Bextra's disapproved use for acute pain. After the FDA failed to respond to Public Citizen's FOIA request, Public Citizen filed suit against the FDA.[39] In litigation, the FDA initially relied on exemption 4 but later released some of the previously redacted material. The material indicated that the drug was associated with a potentially deadly side effect: an increased risk of thromboembolic events—blood clots—in certain patients using Bextra for acute pain. Public Citizen relied on this information in a citizen petition asking the FDA to withdraw approval of the drug,[40] and the FDA later did remove it from the market.[41]

Safety Violations at Food Processing Facilities. Under the Federal Meat Inspection Act, 21 U.S.C. § 601 et seq., the U.S. Department of Agriculture (USDA) has the authority to inspect slaughterhouses and other meat processing facilities to ensure the safety of meat products sold to the public. In 2009, *New York Times* reporter Michael Moss revealed inadequate testing of meat in 2007 that resulted in an *E. coli* outbreak that sickened 940 people.[42] Cargill eventually recalled 844,812 pounds of beef patties following the outbreak.[43] Using FOIA requests,

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[39] *See Public Citizen Health Research Grp. v. FDA*, Complaint, No. 04-cv-304 (D.D.C. Feb. 26, 2004), https://www.citizen.org/system/files/case_documents/acf5cf.pdf.

[40] *See* Public Citizen, Petition to Withdraw Celecoxib & Valdecoxib, *supra* n.23.

[41] FDA, *COX-2 Selective (Includes Bextra, Celebrex, and Vioxx) and Non-Selective Steroidal Anti-Inflammatory Drugs (NSAIDs)*, *supra* n.24.

[42] Michael Moss, *The Burger That Shattered Her Life*, N.Y. Times (Oct. 3, 2009), https://www.nytimes.com/2009/10/04/health/04meat.html.

[43] *Id.*

Moss was able to obtain details from the USDA about Cargill's failure to follow its safety plan.[44] USDA records acquired through FOIA also revealed that in the months before the outbreak, federal inspectors found that Cargill was in violation of safety procedures for handling ground beef.[45] The USDA did not impose any fines or sanctions.[46] In the aftermath of the outbreak, USDA officials promised to "creat[e] a new system to collect and analyze these types of violations" in order to better protect against foodborne illnesses.[47]

Although the USDA withheld some information in response to Moss's FOIA request, it disclosed important information, including that Cargill had not followed its safety plan and had been found to be in violation of safety procedures in the months leading up to the outbreak.[48] Broadening the scope of exemption 4 would limit the public's ability to obtain information about food processing inspections, and thus limit the ability of the public, watchdog groups, and journalists to access vital information about public health and USDA's work to protect it.

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[44] USDA, FSIS Notice of Intended Enforcement (Dec. 14, 2007), https://www.nytimes.com/interactive/projects/documents/food-safety-documents (pp. 2–9).

[45] *See* USDA, FSIS Noncompliance Record No. 007-2007-5950 (July 3, 2007), https://www.nytimes.com/interactive/projects/documents/food-safety-documents (p. 104); USDA, FSIS Noncompliance Record No. 0007-2007-5950 (Aug. 7, 2007), https://www.nytimes.com/interactive/projects/documents/food-safety-documents (pp. 105–06).

[46] Moss, *supra* n.42.

[47] *Id.*

[48] *See* documents cited *supra* at nn.44 & 45. Although Moss also obtained unredacted versions of certain records from a source, Moss, *supra* n.42, this information could be gleaned from the redacted records produced by USDA.

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As these examples demonstrate, disclosure through FOIA of information submitted to the government by commercial entities plays an important role in "hold[ing] the governors accountable to the governed" on issues of public health and safety. *Robbins Tire & Rubber Co.*, 437 U.S. at 242. The Court should reject FMI's proposed broadening of the scope of exemption 4, which would cut off access to vital information, undermining FOIA's objective and diminishing protection for public health and safety.

III. The longstanding construction of exemption 4 is sensible, workable, and reflects the balance Congress struck in creating FOIA exemptions.

Although FMI contends that the *National Parks* competitive harm standard is "unworkable," Pet. Br. 41–43; *see* U.S. Br. 23–24, *National Parks* has been widely adopted by courts across the country, *see* Pet. Br. 38 & nn.23 & 24. Despite FMI's protestations, there is scant evidence in the case law that courts struggle to apply the standard.

As the government acknowledges, the *National Parks* standard has been applied by all federal agencies since at least 1987. *See* U.S. Br. 23. Procedures incorporated into federal agencies' FOIA regulations generally require that an agency "notify[] submitters of a possible disclosure of their information and instruct agencies to consider the grounds that submitters identify for non-disclosure." *Id.* at 23 (quoting Exec. Order 12,600, 3 C.F.R. 235–36 (1987)); *see, e.g.*, 7 C.F.R. § 1.12(a) (USDA); 21 C.F.R. § 20.61(e)(1)–(3) (FDA); 49 C.F.R. § 7.29(a)–(b) (Department of Transportation). Agencies must further "give the submitter a written statement briefly explaining why the submitter's objections are not sustained" and "promptly

notif[y]" the submitter "[w]henever a FOIA requester brings suit seeking to compel disclosure of confidential commercial information." Exec. Order 12,600, 3 C.F.R. 237; *see, e.g.*, 7 C.F.R. § 1.12(d)–(e); 21 C.F.R. § 20.61(e)(3)–(4); 49 C.F.R. § 7.29(b), (e). Thus, before any disclosure, the agency notifies the submitter that it has received a FOIA request, receives the submitter's input, and gives the submitter notice of its decision so that the submitter can seek judicial review if it disagrees. This approach has operated for decades, and the limited number of reverse-FOIA suits speaks to the workability of the system. *See supra* n.4.

FMI's primary complaint about the *National Parks* standard appears to be that "lower courts have 'tended to resolve issues of competitive harm on a case-by-case basis rather than by establishing general guidelines.'" Pet. Br. 42 (quoting U.S. Dep't of Justice Guide to the Freedom of Information Act at 309 (2014), https://www.justice.gov/sites/default/files/oip/legacy/2014/07/23/exemption4_0.pdf). But that a standard—like the standard for assessing an unwarranted invasion of privacy under exemption 6—requires a fact-specific application does not render it "unworkable." Notably, neither FMI nor the government offers evidence that application of the standard has caused competitive harm to submitters.[49]

Thus, as respondent Argus News Leader has explained, the claimed circuit splits on which FMI relies as

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[49] FMI asserts that exemption 4 procedures "sometimes yield the wrong result," but does not explain what it means by that statement and does not offer examples of FOIA disclosures that caused harm, other than the "harm" of spending resources on the FOIA process. Pet. Br. 42–43 & n.28. In any event, FMI's disagreement with unspecified court decisions does not suggest that the standard applied in those decisions is "unworkable."

"proof of *un*workability," Pet. Br. 41, show no more than "courts applying the same test to different facts, resulting in different outcomes." Resp. Br. in Opp. 23. These cases reflect the "balance" struck by Congress in enacting FOIA's "broad provisions favoring disclosure, coupled with the specific exemptions." *John Doe Agency v. John Doe Corp.*, 493 U.S. 146, 153 (1989). Congress could have exempted all information submitted by non-governmental entities or none of it, but Congress instead chose to limit exemption 4 to "trade secrets" and "commercial or financial information" that is "privileged or confidential." 5 U.S.C. § 552(b)(4). That the *National Parks* test strikes a "balance" between disclosure and withholding is evidenced by the fact that the case law contains both numerous decisions ordering disclosure and numerous decisions denying it. *See, e.g.*, *Public Citizen v. U.S. Dep't of Health & Human Servs.*, 66 F. Supp. 3d 196 (D.D.C. 2014); *Public Citizen Health Research Grp. v. FDA*, 185 F.3d 898 (D.C. Cir. 1999).

In contrast, under FMI's proposed standard, requesters would be unlikely ever to prevail in challenging withholding based on exemption 4. And, as explained in Part II, the harm to the public from the dramatically decreased accessibility would be immense.

CONCLUSION

For the foregoing reasons, and the reasons stated in respondent's brief, the decision below should be affirmed.

Respectfully submitted,

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